K060453

MAR 9 2006

510(k) Summary

Submitter
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Date Prepared
08 March 2006

Name of Device
Common Name: PACS Workstation
Proprietary Name: AZE VirtualPlace
Classification Name: Picture Archiving and Communications System
Regulation: 892.2050
Class: II
Product Code: 90 LLZ

Predicate Devices
The AZE VirtualPlace is substantially equivalent in intended use, function, and features to the currently marketed devices:

GE Advantage Workstation 4.3, K052995;
Philips Medical Systems ViewForum 2003, K032096;
MeVis LiverAnalyser / LiverViewer Software from MeVis Technology GmbH & Co. KG, K051528;
QBrain software from Medis Medical Imaging Systems, B.V., K050703;
BrainViewRx Viewer Version 1.0 from Kyron Clinical Imaging, Inc., K052467.

Device Description
The AZE VirtualPlace utilizes DICOM images as it facilitates reviewing, printing, storing, communications, and transferring multi-modality images from a variety of diagnostic imaging systems, such as CT, MR. The AZE VirtualPlace consists of workstation, monitor, keyboard and mouse. The AZE VirtualPlace is provided as basic software with additional software modules available for various features/functions.

Intended Use
AZE VirtualPlace is an image processing workstation that accepts, transfers, displays, stores, and digitally processes DICOM medical images from a variety of diagnostic imaging systems (such as CT, MRI, or from image archives) for viewing, image manipulation, communication, printing and quantification. When interpreted by a trained physician, filmed or displayed images on the VirtualPlace monitor may be used as a basis for diagnosis, except in the case of mammography images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers

at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Technological Characteristics

The AZE VirtualPlace has similar technological characteristics to the currently marketed predicate devices listed above. The AZE VirtualPlace components meet the following standards:

IEC 60950:1994, Safety of Information Technology Equipment

IEC 60601-1-2:2001, Medical Electrical Equipment - PART 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

RFI Emission: EN 55022:1998 Class A: Product family standard

EN61000-3-2:2000 Class D: Limits for harmonic current emission

EN61000-3-3; 1995+a1:2001: Limitation of voltage fluctuation and flicker in low-voltage supply system

Immunity: EN 55024:1998 Product family standard

Digital Imaging and Communications in Medicine (DICOM) Standard (2004)

Joint Photographic Experts Group (JPEG) images are in compliance with ISO/IEC 10918-1 standard

Performance Data (non-clinical or clinical)

The AZE VirtualPlace is substantially equivalent to the predicate devices based on the descriptive data, compliance with standards, software features and indications for use.

Conclusion

The technological characteristics and performance data for the AZE VirtualPlace demonstrates it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2006

AZE, Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K060453
Trade/Device Name: AZE Virtual Place
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 20, 2006
Received: February 22, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: Not assigned K060453

Device Name: AZE VirtualPlace

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801.Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060453